UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

KELLY BERRA, **Plaintiff,** **v.** **JOHNSON & JOHNSON, INC., and** Serve: Johnson & Johnson Registered Agent Address: One Johnson & Johnson Plaza City, State: New Brunswick, NJ 08933 **ETHICON, INC.,** Serve: Ethicon, Inc. Registered Agent Address: Route 22 West, Room M-114 City, State: Somerville, NJ 08876 **Defendants.**	**Case No.: 4:21-cv-00068** **JURY TRIAL DEMANDED**

COMPLAINT

Come Now, Plaintiff Kelly Berra, and for her Complaint against Defendants Johnson & Johnson, Inc., and Ethicon, Inc., alleges as follows:

THE PARTIES

1. Plaintiff Kelly Berra is an adult individual, citizen, and resident of Saint Louis County in the State of Missouri.

2. Defendant Johnson & Johnson, Inc. is a corporation, and according to its website, the world's largest and most diverse medical device and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson organizes its subsidiary businesses into individual Business Units to coordinate the

development, manufacture, testing, marketing promotion, training, distribution and sale of its pelvic floor repair Gynecare TVT® Continence Systems. For diversity purposes, Johnson & Johnson is a citizen of New Jersey.

3. Defendant, Ethicon, Inc., is a wholly owned subsidiary of Defendant Johnson & Johnson with its principal place of business located in Somerville, New Jersey. For diversity purposes, Ethicon, Inc. is a citizen of New Jersey.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action pursuant to the diverse citizenship of the parties. 28 U.S.C. § 1332(a)(2). Plaintiff is a citizen and resident of Missouri. Defendants Johnson & Johnson, Inc. and Ethicon, Inc., have a principal place of business in New Jersey.

5. Personal jurisdiction exists over Defendants in the U.S. and in Missouri due to the general and specific contacts it maintains. Defendants maintain those contacts presently and did so at all times material to this action. Moreover, this Court has specific jurisdiction over this matter as Plaintiff was injured by Defendant's product in Missouri. Finally, the amount in controversy exceeds $75,000.

6. Venue is proper in the Eastern District of Missouri, Eastern Division pursuant to 28 U.S.C. § 1391 as a substantial part of the events and/or omissions giving rise to the Plaintiff's claims emanated from activities within this jurisdiction and Defendants conduct substantial business within this jurisdiction.

FACTUAL ALLEGATIONS

8. Prior to August 17, 2009, Plaintiff Kelly Berra (hereinafter "Plaintiff") was

diagnosed as suffering from stress urinary incontinence, cystocele, and rectocele ("urologic ailments"). These urologic ailments can be surgically addressed using synthetic materials such as "slings" that are placed under the urethra to provide support.

9. On or about August 17, 2009, Plaintiff sought treatment for her urologic ailments and was surgically implanted with a mesh device during a tension-free vaginal tape placement performed by Dr. Enrique Perinetti ("Dr. Perinetti") at Christian Hospital.

10. The tension-free vaginal tape used in Plaintiff's surgery was the Gynecare TVT Device ("TVT"), which was designed, manufactured, and sold by Ethicon, Inc. ("Ethicon, Inc."). The TVT surgically implanted in Plaintiff was from lot number 3289006.

11. After August 17, 2009, Plaintiff continued to suffer from pain and had dyspareunia.

12. Between August 17, 2009 and November 8, 2017, Plaintiff unsuccessfully attempted to alleviate her pain and treat her dyspareunia with a number of medications.

13. On or about November 8, 2017, Plaintiff underwent a revision surgery due to complaints of dyspareunia, vaginal pain, mesh exposure, muscular groin pain, leg pain, vaginal scarring, and foreign material in the vagina. Dr. Dionysios Veronikis ("Dr. Veronikis") at Mercy Hospital resected the TVT Device after dissecting heavy scar tissue and removing it from portions of the pelvis and vagina it adhered to.

14. The surgery did not alleviate Plaintiff's pain and she continued to suffer symptoms worse than what she experienced before her surgery, which required more visits to gynecologists, urologists, and other specialists.

15. Upon information and belief, the pain that Plaintiff suffered after her surgery was caused by the negligent design and manufacture of the TVT that was surgically implanted in her. In addition, the revision and removal surgery that Plaintiff underwent in November 2017, was

necessitated by the negligent design and manufacturing of the TVT in the August 2009 implantation procedure.

16. Plaintiff was forced to undergo extensive medical treatment, including, but not limited to, an operation to excise portions of TVT mesh that were adhered, the use of pain control and other medications.

17. As a direct and proximate result of the foregoing acts and omissions set forth in this Complaint, Plaintiff has:

(a) Suffered severe and permanent injuries which she will be forced to endure for the remainder of her life;

(b) Suffered physical pain and suffering;

(c) Suffered mental pain and suffering;

(d) Had her enjoyment of life severely impaired;

(e) Incurred and will continue to incur lost wages and loss of earning capacity;

(f) Incurred and will continue to incur various sums of money for past, present and future medical expenses associated with monitoring and treating her injuries, including but not limited to corrective surgery and hospitalization; and

(g) Incurred attorney's fees and expenses of litigation related to this action.

COUNT I

STRICT PRODUCT LIABILITY – DEFECTIVE DESIGN OR MANUFACTURE

18. Plaintiff hereby incorporates by reference all above allegations as if fully set forth herein and further state as follows:

19. At all times material hereto, Defendants Johnson & Johnson, Inc. and Ethicon, Inc. engaged in the business of selling, distributing, supplying, manufacturing, marketing and promoting transvaginal mesh devices, including the Gynecare TVT Device, which was defective and unreasonably dangerous to Plaintiff.

20. At all times material hereto, TVT, manufactured by Defendants Johnson & Johnson, Inc. and Ethicon, Inc., was defective and unreasonably dangerous to Plaintiff and other foreseeable users at the time the product left the control of Defendant Ethicon, Inc.

21. At all times material hereto, TVT, manufactured by Defendants Johnson & Johnson, Inc. and Ethicon, Inc., was expected to reach and did reach, consumers, including Plaintiff, without substantial change in the condition in which they were sold.

22. Plaintiff was of the type of patient and consumer that Defendants Johnson & Johnson, Inc. and Ethicon, Inc. could reasonably expect would be prescribed and would use the transvaginal mesh device manufactured by Defendants Johnson & Johnson, Inc. and Ethicon, Inc.

23. TVT, manufactured by Defendants Johnson & Johnson, Inc. and Ethicon, Inc., was defective and unreasonably dangerous when the product was initially patented, when it was subsequently promoted, when it was placed into the stream of commerce and when it was received by Plaintiff in ways which include, but are not limited to, one or more of the following particulars:

(a) When placed into the stream of commerce, TVT contained an unreasonably dangerous design defect and was not reasonably safe to use, as intended, subjecting Plaintiff to risks which exceeded the benefits;

(b) When placed into the stream of commerce, TVT was defective in design and formulation, making use of it more dangerous than an ordinary physician or consumer would expect and more dangerous than other risks associated with the

treatment of pelvic organ prolapse and stress urinary incontinence;

(c) TVT was insufficiently tested;

(d) TVT caused harmful side effects which outweigh any potential utility;

(e) TVT was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff, of the full nature and extent of the risks and side effects of the transvaginal mesh devices that were known or reasonably scientifically knowable at the time the product left the possession of Defendants Johnson & Johnson, Inc. and Ethicon, Inc.;

(f) The warnings or instructions provided by Defendants Johnson & Johnson, Inc. and Ethicon, Inc. were not of a nature that a reasonably prudent medical device company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicated sufficient information on the dangers of the Gynecare TVT Device and its defects, taking into account the characteristics of the products and the ordinary knowledge common to the physicians and the consumers, such as Plaintiff, who purchases the product;

(g) TVT was further defective due to inadequate post-marketing warning or instruction because Defendants Johnson & Johnson, Inc. and Ethicon, Inc. knew of the risk of injury but failed to promptly investigate, respond to, and warn about adverse effects revealed by post-marketing adverse event reports; and

(h) Defendants Johnson & Johnson, Inc. and Ethicon, Inc. knew, or in light of reasonably available scientific knowledge, should have known about the danger that TVT would cause the injuries for which Plaintiff seeks recovery. A

reasonably competent physician using TVT would not realize the dangerous condition of the transvaginal mesh device.

24. The specific nature of the Gynecare TVT Device defects includes, but is not limited to, the following:

(a) the use of polypropylene material in the mesh itself and the immune reaction that results, causing adverse reactions and injuries;

(b) the design of the TVT to be inserted transvaginally into an area of the body with high levels of bacteria, yeast, and fungus that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

(c) the product itself, which is part of the Pelvic Mesh Products, requires to the physician to insert the device "blindly", resulting in nerve damage and damage to other internal organs;

(d) biomechanical issues with the design of the TVT, that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade resulting in injury;

(e) the lack of porosity in the TVT resulting in the formation of a scar plate that prohibits tissue growth, resulting in mesh contraction, nerve damage, pain and erosion of the mesh into other organs, and failure of the device;

(f) the use and design of anchors in the TVT which when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

(g) degradation of the mesh itself over time which causes the internal tissue to degrade resulting injury;

(h) particle loss and or "shedding" of the mesh both during implantation and following implantation that results in additional undesirable complication including an increased inflammatory response and a migration of those particles resulting in injury;

(i) the welding and heating of the TVT itself during production which creates a toxic substance that contributes to the degradation of the mesh and host tissue alike;

(j) the design of trocars, as devices to insert the TVT into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing pain and other injuries;

(k) the propensity of the mesh for "creep", or to gradually elongate and deform when subject to prolonged tension inside the body;

(l) the propensity of the mesh to contract, retract, and/or shrink inside the body;

(m) the inelasticity of the mesh, causing them to be improperly matted to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking); and

(n) the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturer's instructions.

25. As a direct and legal consequence of the defective condition of TVT, Plaintiff has sustained serious and permanent injuries.

26. As a result of the injuries suffered due to the use of TVT, Plaintiff has endured pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants Johnson & Johnson, Inc. and Ethicon, Inc. in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT II

STRICT PRODUCT LIABILITY – FAILURE TO WARN

27. Plaintiff hereby incorporates by reference all above allegations as if fully set forth herein.

28. Defendants Johnson & Johnson, Inc. and Ethicon, Inc.'s transvaginal mesh devices, including TVT, were defective and unreasonably dangerous when they left the possession of Defendants, in that they contained warnings insufficient to alert consumers, including Plaintiff herein, to the dangerous risks and side effects associated with the devices.

29. Plaintiff was implanted with the Gynecare TVT Device for its intended purpose.

30. Plaintiff could not have discovered the defects in TVT through the exercise of care.

31. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. knew or should have known of the dangers associated with TVT and had a continuing duty to counsel and warn Plaintiff of such

dangers.

32. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. failed to adequately warn consumers, including Plaintiff, of the dangers associated with TVT. The warnings that were given by Defendants Johnson & Johnson, Inc. and Ethicon, Inc. were not accurate, adequate, complete, or clear.

33. Gynecare TVT Device is defective due to Defendants Johnson & Johnson, Inc. and Ethicon, Inc.'s failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

(a) TVT's propensity to contract, retract, and/or shrink inside the body;

(b) TVT's propensity for degradation, fragmentation, disintegration and/or creep;

(c) TVT's inelasticity preventing proper mating with the pelvic floor and vaginal region;

(d) the rate and manner of mesh erosion or extrusion;

(e) the risk of chronic inflammation resulting from TVT;

(f) the risk of chronic infections resulting from TVT;

(g) the risk of permanent vaginal or pelvic scarring as a result of TVT;

(h) the risk of recurrent, intractable pelvic pain and other pain resulting from TVT;

(i) the need for corrective or revision surgery to adjust or remove the TVT;

(j) the severity of complications that could arise as a result of implantation of TVT;

(k) the hazards associated with TVT;

(l) TVT's defects described herein;

(m) treatment of stress urinary incontinence and pelvic organ prolapse with the TVT is no more effective than feasible available alternatives;

(n) treatment of stress urinary incontinence and pelvic organ prolapse with the TVT exposes patients to greater risk than feasible available alternatives;

(o) treatment of stress urinary incontinence and pelvic organ prolapse with TVT makes future surgical repair more difficult than feasible available alternatives;

(p) use of the TVT puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

(q) removal of the TVT due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

(r) complete removal of the TVT may not be possible and may not result in complete resolution of the complications, including pain.

34. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. have underreported information about the propensity of TVT to fail and cause injury and complications and has made unfounded representations regarding the efficacy and safety of their transvaginal mesh products, including TVT, through various means and media.

35. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the mesh products, including TVT.

36. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. failed to design and establish a safe, effective procedure for removal of TVT, or to determine if a safe, effective procedure for removal of TVT exists.

37. Feasible and suitable alternatives to TVT have always existed relevant that do not present the same frequency or severity of risks as do the mesh products.

38. TVT was at all times utilized and implanted in a manner foreseeable to Defendants

Johnson & Johnson, Inc. and Ethicon, Inc., as Defendants Johnson & Johnson, Inc. and Ethicon, Inc. generated the instructions for use, created the procedures for implanting the device, and trained the implanting physicians.

39. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. provided incomplete and insufficient training and information to physicians regarding the use of TVT and the aftercare of patients implanted with TVT.

40. Defendant's mesh product, TVT, implanted into Plaintiff, was in the same or substantially similar condition as it was when it left the possession of Defendants, and in the condition directed by and expected by the Defendants.

41. As a direct and legal consequence of the defective condition of Defendants Johnson & Johnson, Inc. and Ethicon, Inc.'s product TVT, Plaintiff has sustained serious and permanent injuries, has endured pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants Johnson & Johnson, Inc. and Ethicon, Inc. in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT III

NEGLIGENCE

42. Plaintiff hereby incorporates by reference all above allegations as if fully set forth herein.

43. At all times relevant to this Complaint, Defendants Johnson & Johnson, Inc. and Ethicon, Inc. had a duty to properly manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain, supply, design and provide proper warnings for the transvaginal mesh devices, including TVT.

44. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. directly or indirectly, negligently and/or defectively, made, created, designed, developed, manufactured, assembled, tested, labeled, supplied, packaged, distributed, promoted, marketed, advertised, warned, and/or sold in interstate commerce, and in the State of Missouri, transvaginal mesh devices, including TVT.

45. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. knew or should have known that the use of TVT created an unreasonable risk of injury as a result of their design, testing, manufacturing, marketing, and inadequate warnings.

46. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. was negligent, and breached duties owed to Plaintiff in the following regards:

(a) Failing to design the TVT so as to avoid an unreasonable risk of harm to women in whom the TVT was implanted, including Plaintiff;

(b) Failing to manufacture the Products so as to avoid an unreasonable risk of harm to women in whom the TVT was implanted, including Plaintiff;

(c) Failing to use reasonable care in the testing of the TVT so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

(d) Failing to use reasonable care in inspecting the TVT so as to avoid unreasonable risk of harm to women in whom the Products were

implanted, including Plaintiff;

(e) Despite knowledge of the danger, failing to adequately warn Plaintiff and/or Plaintiff's physicians that the use of TVT could result in injurious conditions;

(f) Despite the fact that they knew or should have known of the Gynecare TVT Device's dangers, Defendants Johnson & Johnson, Inc. and Ethicon, Inc. willfully and deliberately failed to adequately disclose the known or knowable risks associated with use in conscious disregard of Plaintiff's safety or welfare;

(g) Failing to adequately provide labeling to make known the adverse effects of TVT;

(h) Failing to make a full disclosure of the adverse effects of TVT;

(i) Continuing to manufacture, inadequately label, and market for profit transvaginal mesh devices, including TVT, when the adverse health effects of the devices were known to create a substantial risk to the health of persons using them; and

(j) Failing to exercise the degree of care and caution that a reasonable, prudent manufacturer would exercise in the same or similar circumstances.

47. Furthermore, Defendants Johnson & Johnson, Inc. and Ethicon, Inc. negligently and carelessly breached this duty of care to Plaintiff because it designed its transvaginal mesh devices defectively. The defects include, but are not limited to:

(a) The material is not inert and therefore reacts to human tissues and/or other

naturally occurring human bodily contents adversely affecting patient health;

(b) The mesh material harbors infections that adversely affect human tissues and patient health;

(c) TVT, and the polypropylene material used to produce it, migrate from the location of its implantation, adversely affecting tissues and patient health;

(d) The mesh material abrades tissues, adversely affecting patient health;

(e) TVT, and the polypropylene material used to produce it, regularly fail to perform the purpose of its implantation such that the patient requires removal of the device and repeated treatment and surgery;

(f) TVT, and the polypropylene material used to produce it, contracts which causes an acute inflammatory response and becomes embedded in human tissue over time such that if it needs to be removed due to its various defects; the removal causes damage to organs and tissues, adversely affecting patient health; and

(g) TVT is defective in shape, composition, weight, physical, chemical and mechanical properties, and is inappropriately engineered for use in the human body.

48. As a result of Defendants Johnson & Johnson, Inc. and Ethicon, Inc.'s negligence, their willful and wanton misconduct, and negligent design, their transvaginal mesh device, Gynecare TVT Device, was used by Plaintiff thereby causing Plaintiff to sustain reasonably foreseeable serious and permanent damages and injuries as alleged in this complaint. The negligence of Defendants Johnson & Johnson, Inc. and Ethicon, Inc. was a proximate cause of Plaintiff's harm

and injuries.

49. Defendants Johnson & Johnson, Inc. and Ethicon, Inc.'s conduct fell below the required standard of care in that it failed to comply with the minimal standards of conduct adhered to by reasonably prudent manufacturers of medical devices, and the minimal standards of conduct adhered to by a reasonably prudent manufacturer when preparing consumer warnings and information in connection with medical devices.

50. The negligence described above directly and proximately caused Plaintiff's injuries. Had Defendants Johnson & Johnson, Inc. and Ethicon, Inc. properly designed, adequately tested, properly responded to safety signals, and provided full, complete, clear, truthful, and accurate warnings, Plaintiff's physicians would not have used the Gynecare TVT Device in Plaintiff.

51. As a direct and legal consequence of Defendants Johnson & Johnson, Inc. and Ethicon, Inc.'s negligence, Plaintiff has sustained serious and permanent injuries and has endured pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants Johnson & Johnson, Inc. and Ethicon, Inc. in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT IV

FRAUD AND MISREPRESENTATION

52. Plaintiff hereby incorporates by reference all above allegations as if fully set forth

herein.

53. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. fraudulently, intentionally and/or negligently misrepresented to the public and to Plaintiff, both directly and by and through Plaintiff's physicians, the safety and effectiveness of the transvaginal mesh device, TVT, and/or fraudulently, intentionally, and/or negligently concealed, suppressed or omitted material, adverse information regarding the safety and effectiveness of TVT.

54. Defendants Johnson & Johnson, Inc. and Ethicon, Inc.'s intentional and/or negligent misrepresentations and omissions regarding the safety and efficacy of the transvaginal mesh device, TVT, and its minimal side effects were communicated to Plaintiff directly through promotional materials, advertising, and product inserts. The safety and efficacy of TVT was also intentionally and/or negligently misrepresented to Plaintiff's prescribing physicians with the intent that such misrepresentations would cause TVT to be used in Plaintiff.

55. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. knew or should have known that the representations they were making regarding the transvaginal mesh device's safety, efficacy, and minimal side effects were false.

56. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. made the misrepresentations and/or actively concealed, suppressed, or omitted this material information with the intention and specific desire that Plaintiff, Plaintiff's physicians, and the consuming public would rely on such misrepresentations in selecting its transvaginal mesh device as the treatment for pelvic organ prolapse and stress urinary incontinence. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. knew or should have known that Plaintiff and Plaintiff's physicians would rely upon their false representations.

57. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. made these

misrepresentations and actively concealed adverse information at a time when they, their agents and/or their employees knew, or should have known that the transvaginal mesh devices, including TVT, had defects, dangers, and characteristics that were other than what they had been represented to the medical community and the consuming public, including Plaintiff herein. Specifically, Defendants Johnson & Johnson, Inc. and Ethicon, Inc. misrepresented, concealed, suppressed, or omitted that:

(a) There had been insufficient studies regarding the safety and efficacy of transvaginal mesh devices;

(b) Despite knowing that there had been insufficient or inadequate testing of the devices, they marketed, promoted, and/or sold the devices as if they had been fully and adequately tested, including Plaintiff's implant, TVT;

(c) That Defendants Johnson & Johnson, Inc. and Ethicon, Inc. knew or should have known of reports of severe adverse reactions associated with use of the devices.

58. Adverse event information was strategically minimized, understated, or omitted in order to create the overall impression that the dangers were insignificant and infrequent.

59. The misrepresentations of and/or active concealment, suppression, and omissions by Defendants Johnson & Johnson, Inc. and Ethicon, Inc. were perpetuated directly and/or indirectly by Defendants Johnson & Johnson, Inc. and Ethicon, Inc., their sales representatives, employees, distributors, agents, and/or detail persons.

60. The misrepresentations of and/or active concealment, suppression, and omissions by Defendants Johnson & Johnson, Inc. and Ethicon, Inc. constitute a continuing tort.

61. Through its product inserts, Defendants Johnson & Johnson, Inc. and Ethicon, Inc.

continued to misrepresent the potential risks and complications associated with its transvaginal mesh device, TVT.

62. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. had a post-sale duty to warn physicians and Plaintiff about the potential risks and complications associated with the TVT mesh it manufactured and sold in a timely manner.

63. If Plaintiff and Plaintiff's physicians had known the true facts concerning the risks of the use of TVT, they would not have used the device, and would have instead used one of the safer alternatives or no device at all.

64. The reliance of Plaintiff and Plaintiff's physicians upon the misrepresentations of Defendants Johnson & Johnson, Inc. and Ethicon, Inc. was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities who were in a position to know the true facts concerning the transvaginal mesh device while Plaintiff and her physicians were not in a position to know the true facts, and because Defendants Johnson & Johnson, Inc. and Ethicon, Inc. overstated the benefits and safety of transvaginal mesh devices, and concomitantly downplayed the risks in their use, thereby inducing Plaintiff's physicians to use the Gynecare TVT Device for Plaintiff, in lieu of other, safer alternatives.

65. As a direct and legal consequence of the acts and omissions set forth herein, Plaintiff has sustained serious and permanent injuries including but not limited to: pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants Johnson & Johnson, Inc. and Ethicon, Inc. in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT V

BREACH OF EXPRESS AND IMPLIED WARRANTIES

66. Plaintiff hereby incorporates by reference all above allegations as if fully set forth herein.

67. Defendants Johnson & Johnson, Inc. and Ethicon, Inc., in the marketing, distribution, and sale of transvaginal mesh devices for human use impliedly warranted that they were fit and safe as may be used by physicians.

68. Defendants Johnson & Johnson, Inc. and Ethicon, Inc., in its product labeling, packaging, and promotional materials, expressly warranted to the medical community that transvaginal mesh devices, including TVT, were safe and fit for use in Plaintiff and the general public for the treatment of pelvic organ prolapse and stress urinary incontinence. In actuality, transvaginal mesh devices were not fit, safe, effective, or proper when used by physicians for recommended use, particularly for Plaintiff and her implant, the Gynecare TVT Device.

69. The transvaginal mesh device, TVT, in the composition and condition that it was marketed, distributed, and sold to Plaintiff was unsafe and unfit for use so as to be in breach of the express and implied warranties that it was fit for its intended purposes.

70. Plaintiff and Plaintiff's physicians relied upon the representations of Defendants Johnson & Johnson, Inc. and Ethicon, Inc. concerning the risks of the use of transvaginal mesh device, TVT.

71. The reliance of Plaintiff and Plaintiff's physicians upon the misrepresentations of

Defendants Johnson & Johnson, Inc. and Ethicon, Inc. was justified, among other reasons, because said misrepresentations and omissions were made by individuals and entities that were in a position to know the true facts concerning transvaginal mesh devices while Plaintiff and Plaintiff's physicians were not in a position to know the true facts.

72. Plaintiff and Plaintiff's physicians would not have used TVT, and would have used one of the safer alternatives, or no device at all, had adequate and accurate information regarding transvaginal mesh devices been provided to them.

73. As a direct and legal consequence of the acts and omissions set forth herein, Plaintiff has sustained serious and permanent injuries including but not limited to: pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants Johnson & Johnson, Inc. and Ethicon, Inc. in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT VI

MISSOURI MERCHANDISING PRACTICES ACT

74. Plaintiff realleges and incorporates herein by reference the foregoing allegations of this Complaint as if fully set forth herein and further alleges as follows:

75. Plaintiff brings this action as a consumer pursuant to Mo. Rev. Stat. § 407.025(1).

76. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. was at all times relevant

hereto lawfully doing business in the State of Missouri and this claim arose in Saint Louis, State of Missouri.

77. At all times relevant, Defendants Johnson & Johnson, Inc. and Ethicon, Inc. sold and advertised for sale merchandise or services in trade or commerce its Gynecare TVT Device.

78. During and before the time of the transaction referred to above, Defendants Johnson & Johnson, Inc. and Ethicon, Inc. engaged in unlawful practices as defined in § 407.020 RSMo by misrepresenting the efficacy of their product to physicians and hospitals and by failing to warn of known defects in shape, composition, weight, physical, chemical and mechanical properties. Their product is inappropriately engineered for use in the human body, which can cause debilitating injury and illness.

79. As a direct and proximate result of the aforementioned unfair practices and concealment, omission and suppression of material facts from Plaintiff's physicians and other health care providers, Plaintiff endured pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future.

80. Plaintiff Kelly Berra was directly and proximately harmed by the aforesaid violation of the Missouri Merchandising Practices Act by Defendants Johnson & Johnson, Inc. and Ethicon, Inc. as described above, and she has suffered and will continue to suffer injuries, including but not limited to pain and suffering, disability or physical impairment, mental anguish, inconvenience, loss of capacity for the enjoyment of life experienced in the past or to be experienced in the future, expense of hospitalization, medical and nursing care and treatment, loss of earnings and loss of the ability to earn money in the future

81. Plaintiff has incurred and will incur attorney fees in prosecuting this action for which Defendants Johnson & Johnson, Inc. and Ethicon, Inc. is liable under § 407.025(1) RSMo.

82. The conduct of Defendants Johnson & Johnson, Inc. and Ethicon, Inc. as described above demonstrated willful, wanton and malicious conduct, as well as a complete indifference to or conscious disregard for the safety of Plaintiff and others, thereby justifying an award of punitive damages in such sum which will serve to punish Defendants Johnson & Johnson, Inc. and Ethicon, Inc. and to deter Defendants Johnson & Johnson, Inc. and Ethicon, Inc. and others from like conduct in the future.

WHEREFORE, Plaintiff demands judgment in her favor and against Defendants Johnson & Johnson, Inc. and Ethicon, Inc. in a sum in excess of $75,000, for costs herein incurred, for attorney's fees, and for such other and further relief as this Court deems just and proper.

COUNT VII

PUNITIVE DAMAGES

83. Plaintiff hereby incorporates by reference all above allegations as if fully set forth herein.

84. While performing each of the acts and omissions previously set forth in this Complaint, Defendants Johnson & Johnson, Inc. and Ethicon, Inc. actually knew of the defective nature of its products and the inadequacy of its warnings as set forth herein, yet Defendants Johnson & Johnson, Inc. and Ethicon, Inc. continued to design, manufacture, market, distribute, and sell their products, including TVT, in their defective condition so as to maximize sales and profits at the expense of Plaintiff's health and the health of the consuming public.

85. The acts and omissions of Defendants Johnson & Johnson, Inc. and Ethicon, Inc. involved an extreme degree of risk, given the probability and magnitude of the potential harm, of

causing harm to Plaintiff and others.

86. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. had actual, subjective awareness of the risk of injury posed by its transvaginal mesh devices to consumers such as Plaintiff. A reasonable company in the position of Defendants Johnson & Johnson, Inc. and Ethicon, Inc. would have been aware of the risk of injury posed to consumers by the use of the transvaginal mesh device, TVT. Yet, Defendants Johnson & Johnson, Inc. and Ethicon, Inc. proceeded in conscious disregard to the rights, safety, and welfare of Plaintiff.

87. The acts and omissions of Defendants Johnson & Johnson, Inc. and Ethicon, Inc. demonstrate that they did not care about the peril in which they placed Plaintiff, such that their conduct was grossly negligent and in conscious disregard of the safety of others, including Plaintiff herein.

88. The conduct of Defendants Johnson & Johnson, Inc. and Ethicon, Inc., as set forth above, was willful, wanton, reckless, grossly negligent, malicious, oppressive, and evidenced such an entire want of care as to raise the presumption of a conscious disregard for the rights and safety of consumers, including Plaintiff. Defendants Johnson & Johnson, Inc. and Ethicon, Inc. acted only out of self-interest and personal gain. Such conduct evidences a specific intent to cause harm to Plaintiff as provided under Missouri law.

89. Accordingly, punitive damages should be imposed against Defendants Johnson & Johnson, Inc. and Ethicon, Inc. pursuant to Missouri and other applicable laws to punish and deter Defendants Johnson & Johnson, Inc. and Ethicon, Inc. from repeating or continuing such unlawful conduct. Plaintiff is entitled to recover punitive damages based upon the acts and omissions of Defendants Johnson & Johnson, Inc. and Ethicon, Inc. as specifically pled herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants Johnson & Johnson, Inc. and Ethicon, Inc. as follows:

1. For general damages in a sum exceeding this Court's jurisdictional minimum;
2. For reasonable medical expenses according to proof;
3. For all damages as allowed by law;
4. For prejudgment interest and post judgment interest as allowed by law;
5. For punitive and exemplary damages as allowed by law;
6. For the costs of suit herein incurred; and
7. For such other and further relief as this Court may deem just and proper.

JURY TRIAL AND TRIAL LOCATION REQUEST

Plaintiff by and through her counsel hereby demand a trial by jury on all issues. Plaintiff also hereby requests the site of the trial be Saint Louis, Missouri.

THE SIMON LAW FIRM, P. C.

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